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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,595	06/27/2003	Erkki Ruoslahti		8175

7590 10/14/2004

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,595	RUOSLAHTI ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

eriod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

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1)☒ Responsive to communication(s) filed on *25 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

isposition of Claims

4)☒ Claim(s) *78-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *78-82* is/are allowed.

6)☒ Claim(s) *83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

pplication Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

riority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

ttachment(s)

☒ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20031212*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

1. Applicant's election with traverse of PTCAYGWCA (SEQ ID NO:336) in the reply filed on August 25, 2004 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner in searching more than one amino acid sequence, and especially in searching SEQ ID NOS: 336, 320, and 319. This is not found persuasive because there is no common core structure among the peptides recited in the claims, or among SEQ ID NOS:336, 320, and 319. Searching multiple amino acid sequences would require multiple non-overlapping sequence searches, and this constitutes an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. The Sequence Listing filed June 27, 2003 is approved.

3. The status of the parent applications should be updated in the claim for priority inserted before the first paragraph on page 1 of the specification.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 83 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of a lymph node pathology using a peptide conjugated to a therapeutic agent, does not reasonably provide enablement for treatment of a lymph node pathology using the peptide in unconjugated form or conjugated to a non-therapeutic agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977)

and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is the treatment of lymph node pathologies by administering a peptide which selectively homes to the lymph node. With respect to (2), the prior art of record does not teach or suggest peptides comprising SEQ ID NO:336. Further, the prior art of record does not recognize that mere binding of a compound to a cell or tissue is either a necessary or sufficient condition for treatment of a pathology affecting the cell or tissue. For example, where a pathology is caused by stimulation of a cell receptor, binding of an agonist to the cell receptor would be expected to exacerbate, not to treat, the pathology. With respect to (3), the relative skill of those in the art is high. With respect to (4), it is not possible to predict, in the absence of any testing, whether or not a particular compound can be used to treat a predetermined condition or pathology. With respect to (5), the claims embrace the treatment of any pathology involving lymph nodes. With respect to (6) and (7), there is no direction or guidance as to what pathologies may affect lymph nodes. There is no direction or guidance as to what particular pathologies, among all of those which might affect the lymph nodes, can be treated using a peptide comprising SEQ ID NO:336. There is no direction or guidance as to the manner in which the peptide of SEQ ID NO:336 homes to the lymph nodes, e.g., as to whether the peptide is a receptor ligand, or whether the peptide binds to some other chemical structure present in the lymph nodes, and thus it is not possible to infer or deduce what

treatments might be successful on the basis of a biochemical mechanism. There are no working examples in the specification concerning treatment of lymph node pathologies or concerning treatment with peptides comprising SEQ ID NO:336. With respect to (8), the quantity of experimentation necessary to determine what lymph node pathologies may be treatable using a peptide comprising SEQ ID NO:336 is high, involving essentially random testing of lymph nodes affected by different pathologies until treatment is detected. The necessity for random testing constitutes evidence of undue experimentation. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

5. Claims 78-82, limited to the elected peptide sequence, are allowable over the prior art of record or any combination thereof. The prior art of record does not teach or suggest peptides comprising SEQ ID NO:336. Accordingly, conjugates comprising the peptide and methods of using the peptide are also novel and unobvious over the prior art of record.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
October 5, 2004